K121444

Canon

JUN - 7 2012

5. 510(k) SUMMARY

Submitter:	Canon, Inc. – Medical Equipment Group 30-2 Shimomaruko, 3-chrome Ohta-ku, Tokyo 146-8501 Japan
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Date Prepared:	April 24, 2012 *(Revised June 7, 2012)*
Trade Name:	CSX-20 Flat Panel Detector
Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name:	OWB, JAA 892.1650 Image-intensified fluoroscopic x-ray system
Predicate Device:	K111824 Canon CSX-10 (MQB 892.1650)
Device Description:	The Canon CSX-20 is a digital radiography flat panel detector that can take fluoroscopic and spot radiographic images of any part of the body. It directly converts the X-ray images captured by the sensor into high-resolution digital images. The instrument is a component of an x-ray system and as such cannot be used outside of such a system. This unit converts the X-rays into digital signals. Not intended for mammography applications.
Statement of Intended Use:	The flat panel detector CSX-20 is designed to provide fluoroscopic and spot radiographic images of human anatomy during diagnostic, surgical and interventional procedures. Examples of clinical application may include angiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical-care and emergency room procedures or other imaging applications at the physician's discretion. The device is intended to replace spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.
Summary of Technological Characteristics:	Comparison with the predicate shows the technological characteristics of the CSX-20 are substantially equivalent to the predicate device. The flat panel detector units are functionally identical. The A/D Conversion was modified from 14-bit precision to 16-bit precision to improve the resolution and S/N. This modification allows for improved tonal precision. Grayscale is a function of the A/D conversion. As a result of the A/D conversion modification, the grayscale gradations have quadrupled from the 4096 of the CSX-10 to the 16384 gradations now available with the CSX-20. By modifying the A/D conversion to 16-bits, a maximum frame rate of the 240 fps has been improved. The modifications described above are all related to the change in A/D conversion from 14-bit to 16-bit precision. These modifications have been incorporated into the CSX-20 in an effort to improve the product performance.

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Summary of Non-Clinical /Test Data:	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. Tests include: Performance testing and Software Validation. Electrical safety and Electromagnetic Compatibility testing has been performed. The unit complies with the US Performance Standard for radiographic equipment.
Conclusion:	*Canon, Inc. – Medical Equipment Group* considers the *CSX-20* to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use for the flat panel detector.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc. – Medical Equipment Group
% Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
RICHARDSON TX 75080

JUN - 7 2012

Re: K121444
Trade/Device Name: CSX-20 Flat Panel Detector
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: April 24, 2012
Received: May 15, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: *CSX-20 Flat Panel Detector*

Indications for Use:

The flat panel detector CSX-20 is designed to provide fluoroscopic and spot radiographic images of human anatomy during diagnostic, surgical and interventional procedures. Examples of clinical application may include angiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical-care and emergency room procedures or other imaging applications at the physician's discretion. The device is intended to replace the spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121449